OMB

Display Date 1.5.04
Publication Date 1.6.04
Certifier G. Tinsley

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Nitazoxanide Paste

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by IDEXX Pharmaceuticals, Inc. The NADA provides for veterinary prescription use of an nitazoxanide oral paste for the treatment of equine protozoal myeloencephalitis (EPM).

DATES: This rule is effective [*insert date of publication in the* **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7543, e-mail: *mberson@cvm.fda.gov.*

SUPPLEMENTARY INFORMATION: IDEXX Pharmaceuticals, Inc., 4249–105 Piedmont Pkwy., Greensboro, NC 27410, filed NADA 141–178 for veterinary prescription use of NAVIGATOR (32 percent nitazoxanide) Antiprotozoal Oral Paste for the treatment of EPM caused by *Sarcocystis neurona.* The NADA is approved as of November 18, 2003, and 21 CFR part 520 is amended by adding new § 520.1498 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and

information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(i)), this approval qualifies for 5 years of marketing exclusivity beginning November 18, 2003.

The agency has determined under 21 CFR 25.33(d)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1498 is added to read as follows:

§ 520.1498 Nitazoxanide paste.

(a) *Specifications.* Each milligram (mg) of paste contains 0.32 mg nitazoxanide.

(b) *Sponsor.* See No. 065274 in § 510.600(c) of this chapter.

(c) *Conditions of use in horses*—(1) *Amount.* On days 1 through 5, administer 11.36 mg per pound (/lb) body weight; on days 6 through 28, administer 22.72 mg/lb body weight.

(2) *Indications for use*—For the treatment of equine protozoal myeloencephalitis (EPM) caused by *Sarcocystis neurona.*

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: 12/23/03

57 S/A

[FR Doc. 03–????? Filed ??–??–03; 8:45 am]

BILLING CODE 4160–01–S